

This Page Is Inserted by IFW Operations
and is not a part of the Official Record

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

IMAGES ARE BEST AVAILABLE COPY.

**As rescanning documents *will not* correct images,
please do not report the images to the
Image Problem Mailbox.**



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/841,715	04/25/2001	Herwing Janssen	00-40374-US	6268

7590 07/29/2002
Louis M. Heidelberger
Reed Smith LLP
2500 One Liberty Place
1650 Market Street
Philadelphia, PA 19103-7301

EXAMINER

LEVY, NEIL S

ART UNIT PAPER NUMBER

1616

DATE MAILED: 07/29/2002

7

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

09

Application No.

841715

Applicant(s)

JANSEN

Examiner

NEC Guy

Group Art Unit

1616

7

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on 6/28/02
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 1-26 is/are pending in the application.
- Of the above claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 1-26 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☒ Claim(s) 1-26 are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
 - ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
 - ☐ received in Application No. (Series Code/Serial Number) _____.
 - ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s) 2/34
- ☒ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Interview Summary, PTO-413
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Other _____

Office Action Summary

Applicant's election with traverse of Group I, species of spinosyn A, D and PVM/MA in Paper No. 6 is acknowledged. The traversal is on the ground(s) that there may be a lack of patentable distinction between the Groups. This is not found persuasive because applicant has not explained why the methods, compositions may not be patentably distinct; they may be use in other than the elected Group compositions methods and utility, so we see patentably distinct inventions, as set out in previous Office Action of 6/5/02. however, in the interest of compact prosecution, claim 25, 26 will be considered part of Group I. Claim 27-74 are cancelled, applicant's comments to so do being treated as amendment to cancel.

The requirement is still deemed proper and is therefore made FINAL.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 1-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The "effective amount" is not stated as to what effective for. "Greater than – about" is indefinite (claim 8, 34, please spell out abbreviations at first appearance in claims. (claim 10, 20 "long chain" is indefinite it is unclear what "stabilizers" is intended to encompass (claims 2-9, 11-23 for example) "R" is unspecified in claim 1, or examiner

Art Unit: 1616

is unfamiliar with this element. Same with claim 24 cetareth-20 is a trade name, and generic form should be claimed. Please eliminate duplicative claims: 2=24. There is no antecedent basis for S. spinoso components in claim 1.

Claims 1-24 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. One of ordinary skill in the art would need to perform excessive experimentation to determine efficacious, if any, amounts and combinations of all structures and compounds encompassed by generic claims structure, and/or that of the S. spinosa components. PVM/MA are not clearly identified in the specification. Please provide MSDS, structures or supported description.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily

published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-10, 12-24 are rejected under 35 U.S.C. 102(e) as being anticipated by Snyder--6063771.

Spinosyn and derivatives and carrier are used as the instant compositions to control lice (column 2, line 28-line 9, column 3). Stabilizer, suspending agents, (column 4, B) including colloidal clays, are added, including maleic anhydride crosslinked copolymers of carbopols (column 8, lines 53-58) at about 5%. Preservatives, sodium hydroxide, antioxidants, cetyl-stearyl alcohols, propylene glycol (column 9, and column 10, top and lines 43-45) also included are the instant stearylkonium chlorides (column 12, top). Viscosity adjusters include silicones (column 12, lines 21-27). The composition (Examples) is lethal (Table 1) at 1-10% spinosael concentrations. Eggs are also killed (column 14, line 40). Cetegreth-20 is at column 13, line 4) "BHT" is at column 14, line 32—unspecified preservative.

Claims 1-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Snyder 6063771 in view of Castro et al 6113888 and Vermeer 5653970.

Snyder (above) provides the instant compositions, licicidal/orrmcidal, with formulations for of hair care (column 2, lines 40-43) but does not specify each component at the instantly claimed %, nor is BHT or PVM/MA specifically identifiable. However, Snyder shows the equivalence of the use of each of the instantly claimed components in various formulations and exemplified compositions and at the instant usage ranges. For instance—column 13, lines 28-35 state pH should be adjusted

Art Unit: 1616

between 3-10; thus one in the art would know to add the required amount of NaOH to achieve desired pH. Castro is cited to show that topical application formulations include the instantly claimed PVM-Ma deadiene copolymer (column 1, lines 50-53) equivalent to Snyder's guar gum, and expressly identifying Snyder's generally described ethylene/MA carbopol copolymers. Note that Castro uses the instant formulation components (column 2, line 6-line 53).

Vermeer is cited to show BHT is a common preservative (antioxidant) used in aqueous hair care/skin care/shampoo compositions (column 89, 49, column 104, 6.3.)

There is not distinguishing disclosure of the instant methods as providing any unusual and/or expected results obtaining since the prior art is well aware of the use of spinosyn actives and carriers, emulsifiers, preservatives/thickeners, pH adjusters, conditioners, moisturizers, stabilizers as instantly claimed. The specific base ingredients, weights and additives are result effective parameters subject to control by one with skill in the art.

All critical elements of the instant invention are disclosed.

Thus, it would be obvious to one of ordinary skill in the art desiring to utilize Snyder's lice control composition, with particular ingredients as identified and art recognized, shown by Castro and Vermeer, as commonly utilized for their functions.

The selection of each ingredient is a result effective parameter chosen to obtain the desired effects. It would be obvious to vary the nature of each ingredient to optimize the effects desired.


Applicant has not provided any objective evidence of criticality, non-obvious or unexpected results that the administration of the particular ingredients' or concentrations provides any greater or different level of prior art expectation as claimed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Neil Levy whose telephone number is 308-2412. The examiner can normally be reached on Tuesday- Friday 7:00 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose Dees can be reached on 308-4628. The fax phone numbers for the organization where this application or proceeding is assigned are 305-4556 for regular communications and 305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 308-1235.

Levy:mv
July 16, 2002


NEIL S. LEVY
PRIMARY EXAMINER